

Examiner Requests

The Examiner has requested copies of the documents cited in Applicants' first IDS filing. Applicants are forwarding said documents under separate cover by first class mail.

The Examiner has requested a "short list" of Robert Eric Montgomery applications and patents "corresponding to claims 1,3 to 10 for investigations of a double patenting issue. Applicants herein provide a list of Montgomery patents and applications of which Applicants are currently aware that may be responsive the Examiner's request. Copies of these references will be provided under separate cover in a supplemental IDS:

09/233,793
US2001/0021374 A1
5,738,843
5,816,802
5,908,614
5,922,307
5,944,528
6,162,055
6,221,341
6,281,265B1
6,312,670 B1
6,322,773 B1
6,331,292

Inventorship Issues Raised Under 35 USC 102(g) and 102(f)

Applicants note that the Examiner made several observations related to inventorship issues in relation to US Patent 6,162,055 (Montgomery IV) and WO 99/40870A1 (Montgomery III). Applicants understand the Examiner's observations to be that since the cited disclosures contain overlapping subject matter with the present application and different inventive entities than the present application, inventorship issues have arisen in relation to those references and the present application. Applicants herein state that R. Eric Montgomery and Salim Nathoo are the inventors of the subject matter of the current pending claims in this

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application. The disclosures of the cited references contain subject matter directed to light-generating devices in addition to subject matter that may overlap the presently pending claims. The additional named inventor, Cipolla, is included on Montgomery III because that application includes claims to the light-generating devices, for which he is a co-inventor. Inventor Cipolla was originally named in the application leading to Montgomery IV because that application also included device claims. Montgomery IV, however, issued without device claims and inventorship was amended to remove Cipolla. Applicants note that Montgomery IV has the same named inventors as the present application, which derives from Montgomery IV.

Since the pending claims of the current application do not contain claims directed to light-generating devices, inventorship in the current application is properly limited to Montgomery and Nathoo, the same inventive entity as the '055 Patent. Thus, the cited references include a different inventor in their disclosures because that inventor's contribution was associated with light-generating devices, unlike the subject matter of the present invention.

Rejections Based on 35 USC 102(e)

The Examiner rejected claims 1-14 under 35 USC 102(e), based on US 6,162,055.

Applicants respectfully disagree with the Examiner's assertions and traverse the rejection. Applicant reminds the Examiner that the '055 patent and the present application are related as parent and child, and thus have the same effective filing date and the same inventive entity, as stated above. Therefore, Applicants submit that a 102(e) rejection based on the '055 patent is improper. For similar reasons, Montgomery III is not proper prior art as against the current application.

Rejections Based on Obviousness and Anticipation

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The Examiner has rejected claims 1-14 as anticipated under 35 USC 102(b) or obvious under 35 USC 103(a) in relation to a plethora of cited references and raised issues under 102 (a), 102(g), 102(f), and 103(c).

Applicant herein traverses each and every rejection and objection of the Examiner in relation to the pending claims to the extent they are understood. Applicants respectfully submit that this Amendment and Response addresses and traverses each and every rejection and objection asserted by the Examiner. In the event that the Examiner finds that Applicant has failed to address a rejection or objection raised in the Office Action of 8 August 2001, Applicant respectfully requests that the Examiner set forth with clarity the grounds and arguments corresponding to the inadvertently omitted rejection(s) or objection(s).

Applicants traverse the Examiner's anticipation rejections of claims 1-14 based on the cited references. The Examiner has not pointed to any evidence in the cited references relating the subject matter of those references to ***transparent*** tooth whitening compositions ***for use with light-activated tooth whitening***. The present invention claims transparent tooth whitening compositions comprising components that, when exposed to actinic light, activate tooth whitening. Applicants submit that merely because the disclosure of the current invention includes carboxypolymethylene and peroxides or peroxyacids, an anticipation rejection does not *ipso facto* arise with regard to the current claims. Rather, the Examiner has a burden to establish a prima facie case of obviousness or anticipation, and has not met this burden. The Examiner has failed to cite any portions of the asserted references that teach, suggest, or motivate combining the references to arrive at the present invention. Applicants respectfully request that the Examiner thus withdraw the anticipation rejection based on the cited patents.

Applicants submit that Montgomery III (WO 99/40870A1) and Montgomery IV (US 6,162,055) cannot be the basis of proper rejections for the reasons stated above.

Applicants submit that Montgomery I (US 5,908,614) and Montgomery II (US 5,922,307), taken alone, together, or in combination with any of the other cited references, do

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not anticipate the present invention or render it obvious. Further, Applicants submit that the Examiner has not met the burden of establishing a prima facie case of anticipation or obviousness in connection with these references, taken alone, together, or in combination with any of the other cited references. The '614 patent is directed to *dry* animal oral care compositions. The '307 patent is directed to *methods* of tooth whitening. The present invention is directed to transparent *compositions* for use in light-activated tooth whitening. The Examiner has not shown how any of the cited references teach, suggest, or motivate combining of references to arrive at the present invention. Applicants assert that mere assertions by the Examiner that combining references should be "obvious" does not suffice to establish a prima facie case of obviousness.

Rejections Under 103(a) and 102(e)

The Examiner rejected claims 1-14 under 103(a), asserting that the claims of the present invention are obvious in light of US 6,162,055, which the Examiner indicated has an earlier effective filing date "constitutes prior art under 35 USC 102(e)." The Examiner has also asserted that claims 1-14 are "directed to an invention not patentably distinct from claims 1 to 12 of commonly assigned 6,162,055. Specifically, they overlap in scope."

Applicants respectfully traverse the Examiner's rejection. Applicants respectfully submit that the cited reference does not have an earlier effective filing date than the current application, but instead remind the Examiner that the cited reference is the parent application of which the present application is a divisional application. Both the cited reference (the parent) and the present application have the same effective filing date because it claims priority to the same application as the parent now cited against it. See present application, page 1. The present application was filed during the pendency of the parent application. See, Preliminary Amendment, August 3, 2000. Further, Applicants submit that the parent application and the present application have the same inventive entity. Applicants thus respectfully submit that the present rejection is improper, and request the Examiner to withdraw all rejections predicated upon employing 6,162,055 as prior art against the present application.

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Obviousness-Type Double Patenting

The Examiner has raised an obviousness-type double patenting rejection of the present application over US Patent 6,162,055, US 5,922,307, and US Patent 5,908,614. An obviousness-type double patenting rejection was also raised over US Patent 5,922,307 and US Patent 5,908,614.

Applicants respectfully disagree with the Examiner's assertions and traverse the rejection. The '055 patent is directed to tooth whitening *methods*, whereas the present invention is directed to *compositions* for use in light-activated tooth whitening. The '307 patent is also directed to tooth whitening *methods*, whereas the present invention is directed to *compositions* for use in light-activated tooth whitening. The '614 is directed to *dry* oral care compositions for animals. The claims of the present invention contain no such limitation. Applicants respectfully request that the Examiner withdraw the double patenting rejections.

35 USC 121 Restriction Requirement

The Examiner made a restriction requirement on the ground of an alleged "plurality of disclosed patentably distinct species."

Applicants traverses the restriction requirement and requests reconsideration. However, in order to fulfill the requirement of 35 USC 121, Applicants provisionally elect claims 1-5 and 7-13, comprising metal-ligand complexes as a photo activating component, hydrogen peroxide as an oxidizing compound, and a gel comprising carboxypolymethylene.

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Filing Date: August 30, 2000

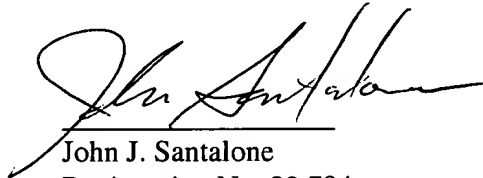
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Conclusion

In light of Applicants's amendments and remarks, Applicants respectfully submit that this application is in condition for further examination or allowance. If there are any questions or comments relating to the present application, the Examiner is respectfully invited to contact Applicants's attorney at the telephone number below. No fee other than the fee for the three-month extension of time is believed to be necessary. If any additional fee is required, or overpayment has been made, please charge, or credit, our Deposit Account No. 11-0171 for such sum.

Respectfully submitted,

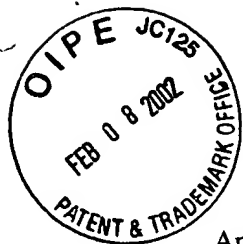
A handwritten signature in dark ink, appearing to read "John J. Santalone", is written over a horizontal line.

John J. Santalone

Registration No. 32,794

Tel: (212) 813-1600

Fax: (212) 813-9600



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Montgomery *et al.*

Examiner: Shep Rose

Filing Date: August 30, 2000

Group Art Unit: 1614

Serial No.: 09/651,170

Docket: 12080-4

For: Light Activated Tooth Whitening Composition and Method of Using Same

Kalow & Springut LLP
488 Madison Avenue
New York, New York 10022

February 8, 2002

Commissioner for Patents
Washington, D.C. 20231

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MARK-UP OF AMENDMENTS PURSUANT TO 37 CFR 1.121

Please amend the above-identified application as follows:

IN THE SPECIFICATION:

Please delete the first paragraph of page 21, consisting of lines 1-14, and replace it with the following paragraph:

The pellicle staining broth was prepared by adding 1.02 grams of instant coffee, 1.02 grams of instant tea, and 0.75 grams of gastric mucin (Nutritional Biochemicals Corp., Cleveland OH 44128) to 250 ml of sterilized trypticase soy broth. Approximately 50 ml of a 24-hour *Micrococcus luteus* culture was also added to the stain broth. The apparatus, with the enamel specimens attached and the staining broth in the trough was then placed in an incubator at [370 C.] thirty-seven degrees Centigrade with the specimens rotating continuously through the staining broth and air. The staining broth was replaced once every 24 hours for ten consecutive days. With each broth change the trough and specimens were rinsed and brushed with deionized water to remove any loose deposits. On the eleventh day the staining broth as modified by the addition of 0.03 grams of $\text{FeCl}_3 \cdot 6\text{H}_2\text{O}$, and this was

continued with daily broth changes until the stained pellicle film on the specimens was sufficiently dark. Then the specimens were removed from the staining broth, brushed thoroughly with deionized water, and refrigerated in a humidor until used.

IN THE CLAIMS:

Please amend the claims as follows:

1. (Amended) A tooth whitening composition for use in light-activated tooth whitening, comprising:
a transparent first component being a carrier compound; and
a transparent second component being an oxidizing compound which when applied to a stained tooth and exposed to actinic light is activated to facilitate tooth whitening.
2. (Amended) A composition as set forth in claim 4 wherein said peroxyacid precursor is selected from a group consisting of [glycerol] glyceryl triacetate, acetylated amino acids, acetylsalicylic acid and [tetraacetylethyldiamine] tetraacetylethyldiamine.

Respectfully submitted,



John J. Santalone
Registration No. 32,794
Tel: (212) 813-1600
Fax: (212) 813-9600